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Remarks

Applicant has amended claims 1 and 17 to contain the allowable subject matter of claims 2 and 19, respectively, and has canceled claims 2 and 19. (Claims 4-6 and 20 were also canceled.) Eighteen (18) claims remain pending in the application, claims 1, 3, 7-18, and 21-24, of which claims 1 and 17 are independent.

In the Advisory Action mailed October 4, 2004, the Examiner indicated that claim 2 would be allowable if submitted in a separate, timely filed amendment. On October 12, 2004, Examiner Machuga and applicants' representative had a brief conversation to address the question of claim 19, which contains similar subject matter as claim 2, and which was not addressed in the Advisory Action. The Examiner indicated that claims 2 and 19 should have been indicated as allowable in section 4 of the Advisory Action.

As claim 1 has been amended to contain the allowable subject matter of claim 2, and claim 17 has been amended to contain the allowable subject matter of claim 19, the applicants believe these amendments place these independent claims in condition for allowance. As all the remaining pending claims depend from claim 1 or 17, these claims should also be allowable.

Repeated below, for convenience, are the remarks made in the Amendment filed August 17, 2004, in response to the final Office action mailed April 19, 2004.

In the Final Office action mailed April 19, 2004, all claims were rejected under 35 U.S.C. 103(a) as being unpatentable (obvious) over Schulman et al (WO 98/37926) in view

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of Silverstone U.S. Patent No. 6161044, with some of these rejections being further in view of various additional art.¹

Applicants have herein amended the independent claims to stipulate that the stimulator or stimulating means is *implanted in an anterolateral area of the spine*. The cited art does not teach or suggest implanting a stimulator/stimulation means in an anterolateral area of the spine.

Page 3 of the Office action states:

Silverstone teaches that the lateral spinothalamic tract is a known pathway for pain impulses and that stimulation along the pathways that carry those impulses can relieve pain (column 1, lines 58-67 and column 2 lines 1-10). This region is near or "adjacent to" the ventral commissure.

Applicants agree that Silverstone column 1, lines 58-67 and column 2 lines 1-3 discuss conduction of pain impulses, including via the lateral spinothalamic tract. However, a careful reading of the lines beginning at column 2 line 4 reveals that Silverstone is discussing how *the body* can inhibit these pain impulses (emphasis added):

Inhibition (or modulation) of pain, *by the body*, can occur anywhere from the point of origin of the pain through the successive synaptic junctions in the pain's central pathway.

¹ Claims 1 and 13-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Silverstone U.S. Patent No. 6161044; claim 3 was rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (10 98/37926) in view of Silverstone as applied to claim 1 above, further in view of Zilber U.S. Patent No. 3822708; claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Silverstone as applied to claim 1 above, further in view of King U.S. Patent No. 6058331; claims 9 and 10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Silverstone as applied to claim 1 above, further in view of Feler et al U.S. Patent No. 6002964; claims 11 and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Silverstone as applied to claim 1 above, further in view of MacDonald et al U.S. Patent No. 5776170; and claims 17, 18 and 21-24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO 98/37926) in view of Silverstone as applied to claim 1 above, further in view of Schulman et al U.S. Patent No. 5358514.

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Applicants note, however, that the device-applied stimulation that *is* contemplated by Silverstone is not provided by an implanted device. In the "Summary of the Invention" at column 6 lines 21-23, Silverstone describes his invention as:

providing methods for the non-invasive treatment, control and/or prevention of various disease conditions and disorders using transcutaneous electrical stimulation....

The entire Silverstone reference is directed to transcutaneous stimulation. For instance, see the "Detailed Description of the Invention" column 7 lines 62-65 and column 8 lines 45-47. There is no teaching or suggestion in Silverstone to apply this transcutaneous stimulation to nerves and tissue of the anterolateral spinal cord, and certainly no teaching or suggestion to implant a stimulator in the anterolateral area of the spine, as there is no teaching or suggestion to implant a stimulator *at all*. As MPEP 2143.03 explains, "all the claim limitations must be taught or suggested by the prior art." Yet, neither the Schulman et al nor the Silverstone reference teach or suggest implanting a stimulator/stimulation means in an anterolateral area of the spine.

Based on MPEP 2143, "Basic Requirements of a *Prima Facie* Case of Obviousness" such requirements have not been met, as there is no basis in the art for combining the Silverstone reference with the Schulman et al reference. MPEP 2143.01 teaches that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." In this instance, the references cannot even be properly combined. MPEP 2143.01 warns that "[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification" and that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." The proposed

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combination of Schulman et al and Silverstone would change the principle operation of both Schulman et al (involving an Implanted device) and Silverstone (involving an external device) and render them unsatisfactory for their intended purposes. For this and other reasons, a *prima facie* case of obviousness has not been established.

This ends the remarks, provided for convenience, from the Amendment filed August 17, 2004, in response to the final Office action mailed April 19, 2004.

Conclusion

Applicants have made an earnest effort to place this application in condition for allowance, following guidance in the Advisory Action and from the Examiner. The Examiner is invited to telephone the undersigned, Laura H. Bishop, at his convenience should any issues remain after consideration of this response, in order to permit early resolution of the same.

Respectfully Submitted,

2004 Oct 15
Date

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